ONLY CONGRESS CAN CHANGE THE LAW TO GIVE FDA THE AUTHORITY TO REGULATE CIGARETTES

FDA Commissioner Kessler has announced that he has determined that FDA has jurisdiction over cigarettes. FDA proposed regulations, which include advertising restrictions and limitations on the sale and distribution of cigarettes, are a misguided effort that is contrary to law. Only Congress can change the law to give FDA the authority to regulate cigarettes.

THE FOOD, DRUG AND COSMETIC ACT DOES NOT GRANT THE FDA JURISDICTION OVER CIGARETTES

1. FDA is the agency charged with overseeing the safety of the nation's medicines and other therapeutic agents. Its authorizing statute, rules, and regulations are all designed to permit the agency to carry out this purpose. The sole source of the FDA's legal authority to regulate products is the Food, Drug, and Cosmetic Act (FFDCA). Under the FFDCA, the FDA can regulate products as "drugs" or "devices" only if they are "intended for use in the . . . treatment or prevention of disease in man . . . [or] . . . [intended] to affect the structure or function of the body of man." 21 U.S.C. §§ 321(g) and (h).

2. The fact that a product may have a pharmacological effect on the body (and thus to some laymen may be said to contain a "drug") does not give FDA jurisdiction to regulate that product. In the specific context of cigarettes, the courts have ruled that the fact that a product may have an "affect on the structure or function of the body" is not enough to establish jurisdiction. Federal Trade Commission v. Liggett & Myers Tobacco Co., 108 F. Supp. 573, 576 (S.D.N.Y. 1952) aff'd, 203 F.2d 955 (2nd Cir. 1953) (court denied jurisdiction over cigarettes under language in the FTC Act identical to the FFDCA standard).

3. FDA "drug" or "device" regulation is authorized only where the manufacturer has made therapeutic claims in the promotion of the product. United States v. Articles of Drug for Veterinary Use, 50 F.3d 497 (8th Cir. 1995). As the courts have held many times, whether a product is intended for use as a therapeutic agent (medicine) -- and subject to FDA jurisdiction -- "is determined from objective evidence such as the product's current and past containers, instructions, and advertisements." See, e.g., Estee Lauder, Inc. v. Food and Drug Administration, 727 F. Supp. 1, 2 (D.D.C. 1989). For example, coffee and colas, which contain caffeine, are not regulated as "drugs"; but caffeine pills, which are marketed as a medicine to keep consumers awake, would be regulated by FDA.

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4. In the specific context of cigarettes, both the FDA and the courts have therefore recognized that cigarettes sold only for smoking pleasure, without any claimed therapeutic or bodily benefit, are not subject to FDA jurisdiction. Action on Smoking and Health v. Harris, 655 F.2d 236, 237 (D.C. Cir. 1980).

5. In fact, for more than 80 years, FDA (and its predecessor agencies) have consistently taken the position before Congress and the courts that FDA does not have any jurisdiction to regulate cigarettes unless the manufacturer makes an express claim of some therapeutic benefit.

FDA CANNOT IMPLEMENT THE REGULATIONS PROPOSED BY FDA

The inapplicability of the FFDCA can be further demonstrated by the absurd results that would occur if FDA tried to apply that law to cigarettes as it is applied to "drugs" or "devices."

1. The FFDCA requires that manufacturers of new drugs and devices prove that the product is both "safe and effective" for some therapeutic purpose. Commissioner Kessler, however, has stated that FDA would never make such a finding for cigarettes. See, e.g., 3 Health Law Reporter (BNA) at 375 (March 24, 1994) ("I am convinced that this finding of 'safety and effectiveness' would not be made by this agency and that therefore such a product [cigarettes] could not be approved as a new drug.") The Institute of Medicine has likewise concluded that "an inevitable effect of classifying nicotine-containing tobacco products as 'drugs' would be to ban them." Institute of Medicine, "Growing Up Tobacco Free" at 235 (1994).

2. While dictating the content of labels for true "drugs" and "devices" is an integral part of normal FDA regulation, the Agency would have no authority to regulate the labeling of cigarette packages with respect to the health warnings (even if it had jurisdiction over the product, which it does not). Under the Federal Cigarette Labeling and Advertising Act, Congress retains exclusive control over the content of health warnings on cigarette packages. As the Supreme Court has stated, FCLAA prohibits "federal rulemaking bodies from mandating particular cautionary statements on cigarette labels . . ." Cipollone v. Liggett Group Inc., 112 S. Ct. 2608, 2618-19 (1992). Further, Congress has delegated authority to oversee the implementation and enforcement of these warnings to the Federal Trade Commission -- not to FDA.

3. If FDA classified cigarettes as over-the-counter "drugs", FDA would not be able to restrict or limit the advertising of cigarettes. The FTC has the sole responsibility for regulating advertising of over-the-counter drugs. Also, if FDA classified cigarettes as over-the-counter drugs, FDA would not be able to limit the distribution of cigarettes.

4. If FDA regulated cigarettes as "devices" that deliver nicotine, it would lack the authority to regulate either their advertising or the distribution.

CONGRESS HAS MADE CLEAR THAT FDA HAS NO JURISDICTION OVER CIGARETTES

The inapplicability of the food and drug laws to cigarettes is not simply a matter of prior court decisions and agency interpretation. It is also compelled by other acts of Congress.

1. Congress has unambiguously expressed its intention to maintain primary control over the health aspects of tobacco products. In 1965, Congress passed the Federal Cigarette Labeling and Advertising Act ("FCLAA"). The purpose of the FCLAA was "to establish a comprehensive Federal Program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." 15 U.S.C. § 1331. This comprehensive scheme has been reconsidered many times, but Congress has consistently determined that cigarettes should be available to the public under a framework that excludes any role for the FDA in regulating the tobacco industry.

2. The decision by FDA to regulate cigarettes contradicts this clear congressional intent. As one congressional report summed up the precedent in this area, "the clear mandate of Congress that the basic regulation of tobacco and tobacco products is governed by legislation dealing with the subject, the Cigarette Labeling and Advertising Act . . ., and that any further legislation in this sensitive and complex area must be reserved for specific Congressional action." S. Rep. No. 251, 94th Cong., 2d Sess. 43, reprinted in, 1976 U.S. Code Cong. & Admin. News, 993, 1012.

3. In fact, over the past 40 years, Congress has considered 20 bills that would have extended FDA's jurisdiction to cigarettes. Supporters of these bills recognized that FDA has no authority to regulate cigarettes. None of the bills passed; and in 69 other amendments to the FFDCA, Congress has never extended FDA jurisdiction to cigarettes.

4. FDA itself has told Congress repeatedly, and Congress has understood, that FDA has no authority to regulate cigarettes under the FFDCA. As the Supreme Court has stated: "[O]nce an agency's statutory construction has been 'fully brought to the attention of the public and the Congress,' and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned." United States v. Rutherford, 442 U.S. 544, n.10 (1979) (emphasis added).

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FDA REGULATION OF CIGARETTES -- FOR ANY PURPOSE -- CAN ONLY BE ACCOMPLISHED BY THE ENACTMENT OF NEW LEGISLATION

1. Commissioner Kessler has tried to "create" FDA jurisdiction by raising the issue of youth smoking. But Commissioner Kessler's stated desire to protect youth cannot create jurisdiction where none exists. See National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334-359 (2d Cir. 1977) (FDA Commissioner's desire to protect the public health must be in accordance with the statutory definition); American Pharmaceutical Ass'n v. Weinberger, 377 F. Supp. 824, 831 (D.D.C. 1974) (public policy problems could not "justify a federal agency of limited jurisdiction from implementing unique control situations not authorized by Congress.")

2. Commissioner Kessler's proposal to regulate tobacco products represents a radical change in direction and departure from long-standing past precedent and practice. Such a proposal raises, by the Commissioner's own acknowledgment, "societal issues of great consequence and magnitude." (See 2/25/94 letter from Dr. Kessler to Coalition on Smoking OR Health ("COSH").) Congress -- not Commissioner Kessler -- must make a national policy decision of such magnitude.

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